March 28, 2003

ENGROSSED
HOUSE BILL No. 1438

DIGEST OF HB 1438 (Updated March 26, 2003 2:11 PM - DI 104)

Citations Affected: IC 25-26; IC 35-48.

Synopsis: Pharmacy matters. Changes pharmacist intern and extern registration renewal time frames. Specifies allocation of pharmacist licensure fees. Removes the expiration provision that allows pharmacists to refill prescriptions in emergencies. Removes the responsibility of the state police department for the controlled substance prescription monitoring program and assigns those responsibilities to the controlled substances advisory committee and the health professions bureau.

Effective: Upon passage; July 1, 2003.

Welch, Brown C, Hasler, Becker
(SENATE SPONSORS — DILLON, SKINNER)

January 14, 2003, read first time and referred to Committee on Public Health.
January 30, 2003, amended, reported — Do Pass.
February 3, 2003, read second time, ordered engrossed. Engrossed.
March 6, 2003, read third time, passed. Yeas 92, nays 0.

SENATE ACTION

February 11, 2003, read first time and referred to Committee on Health and Provider Services.
March 27, 2003, amended, reported favorably — Do Pass.

March 28, 2003

First Regular Session 113th General Assembly (2003)

PRINTING CODE. Amendments: Whenever an existing statute (or a section of the Indiana Constitution) is being amended, the text of the existing provision will appear in this style type, additions will appear in **this style type**, and deletions will appear in ~~this style type~~.

Additions: Whenever a new statutory provision is being enacted (or a new constitutional provision adopted), the text of the new provision will appear in **this style type**. Also, the word **NEW** will appear in that style type in the introductory clause of each SECTION that adds a new provision to the Indiana Code or the Indiana Constitution.

Conflict reconciliation: Text in a statute in *this style type* or ~~*this style type*~~ reconciles conflicts between statutes enacted by the 2002 Regular or Special Session of the General Assembly.

ENGROSSED HOUSE BILL No. 1438

A BILL FOR AN ACT to amend the Indiana Code concerning professions and occupations.

Be it enacted by the General Assembly of the State of Indiana:

SECTION 1. IC 25-26-13-4.5 IS AMENDED TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2003]: Sec. 4.5. (a) As used in this section, "impaired pharmacist" means a licensed pharmacist who has been affected by the use or abuse of alcohol or other drugs.

(b) The board shall assist in the rehabilitation of an impaired or a licensed pharmacist. The board may:

(1) enter into agreements, provide grants, and make other arrangements with statewide nonprofit professional associations, ~~or~~ foundations, **or entities specifically devoted to the rehabilitation of impaired health care professionals** to identify and assist impaired pharmacists or licensed pharmacists; and

(2) accept and designate grants, public and private financial assistance, and licensure fees to fund programs under subdivision (1).

(c) Except as provided in subsection (e), all:

(1) information furnished to a nonprofit professional organization or foundation, including interviews, reports, statements, and

memoranda; and

(2) findings, conclusions, or recommendations that result from a proceeding of a professional organization or foundation;

are privileged and confidential.

(d) The records of a proceeding under subsection (c) may be used only in the exercise of the proper functions of the board and may not become public records or be subject to a subpoena or discovery proceeding.

(e) Information received by the board from the board designated rehabilitation program for noncompliance by the licensed pharmacist may be used by the board in any disciplinary or criminal proceedings instituted against the impaired licensed pharmacist.

(f) The board designated rehabilitation program shall:

(1) immediately report to the board the name and results of any contact or investigation concerning an impaired licensed pharmacist that the program believes constitutes an imminent danger to either the public or the impaired licensed pharmacist; and

(2) in a timely fashion report to the board an impaired licensed pharmacist:

(A) who refuses to cooperate with the program;

(B) who refuses to submit to treatment; or

(C) whose impairment is not substantially alleviated through treatment.

SECTION 2. IC 25-26-13-10, AS AMENDED BY P.L.187-1999, SECTION 3, IS AMENDED TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2003]: Sec. 10. (a) An applicant for registration as a pharmacist intern or pharmacist extern must furnish proof satisfactory to the board that the applicant is a high school graduate or its equivalent, has obtained a general educational development (GED) diploma, or is enrolled in a pre-pharmacy or pharmacy curriculum at an accredited school of pharmacy. The board may require the applicant to successfully complete an examination prior to registering the applicant as a pharmacist intern or pharmacist extern.

(b) A registration issued under subsection (a) of this section is valid for ~~six (6) years from the date of issuance~~ **one (1) year** and may be renewed by the board for an additional ~~five (5) years for good cause shown.~~ **year until the expiration date established by the health professions bureau under IC 25-1-5-4.**

(c) An application for registration or renewal must be accompanied by the appropriate fee.

SECTION 3. IC 25-26-13-23 IS AMENDED TO READ AS

FOLLOWS [EFFECTIVE JULY 1, 2003]: Sec. 23. (a) The board shall establish appropriate fees to carry out this chapter.

(b) All fees are nonrefundable. A receipt shall be issued for all fees and fines submitted.

(c) All fees collected under this section ~~and fines collected under IC 25-1-9~~ shall be transferred to the treasurer of state and deposited in the general fund of the state.

~~(d) The board may adopt rules that provide that at the time of license renewal, each licensed pharmacist pay an additional fee not to exceed ten dollars ($10). The amounts collected under this subsection shall be deposited in the impaired pharmacists account established under section 30 of this chapter.~~ **(d) A fine collected by the board shall be transferred to the treasurer of state and deposited in the state general fund.**

(e) At the time of license renewal, each licensed pharmacist shall pay a renewal fee, a part of which shall be used for the rehabilitation of impaired pharmacists. Notwithstanding subsection (c), the lesser of the following amounts from fees collected under this subsection shall be deposited in the impaired pharmacists account of the state general fund established by section 30 of this chapter:

(1) Sixteen percent (16%) of the license renewal fee for each license renewed under this section.

(2) The amount per license needed to operate the impaired pharmacists program, as determined by the health professions bureau.

SECTION 4. IC 25-26-13-25, AS AMENDED BY P.L.1-2002, SECTION 98, IS AMENDED TO READ AS FOLLOWS [EFFECTIVE UPON PASSAGE]: Sec. 25. (a) All original prescriptions, whether in written or electronic format, shall be numbered and maintained in numerical and chronological order, or in a manner approved by the board and accessible for at least two (2) years in the pharmacy. A prescription transmitted from a practitioner by means of communication other than writing must immediately be reduced to writing or recorded in an electronic format by the pharmacist. The files shall be open for inspection to any member of the board or its duly authorized agent or representative.

(b) Except as provided in subsection (c) before the expiration of subsection (c) on June 30, 2003, a prescription for any drug, the label of which bears either the legend, "Caution: Federal law prohibits dispensing without prescription" or "Rx Only", may not be refilled without written or oral authorization of a licensed practitioner.

(c) A prescription for any drug, the label of which bears either the legend, "Caution: Federal law prohibits dispensing without prescription" or "Rx Only", may be refilled by a pharmacist one (1) time without the written or oral authorization of a licensed practitioner if all of the following conditions are met:

(1) The pharmacist has made every reasonable effort to contact the original prescribing practitioner or the practitioner's designee for consultation and authorization of the prescription refill.

(2) The pharmacist believes that, under the circumstances, failure to provide a refill would be seriously detrimental to the patient's health.

(3) The original prescription authorized a refill but a refill would otherwise be invalid for either of the following reasons:

(A) All of the authorized refills have been dispensed.

(B) The prescription has expired under subsection (f).

(4) The prescription for which the patient requests the refill was:

(A) originally filled at the pharmacy where the request for a refill is received and the prescription has not been transferred for refills to another pharmacy at any time; or

(B) filled at or transferred to another location of the same pharmacy or its affiliate owned by the same parent corporation if the pharmacy filling the prescription has full access to prescription and patient profile information that is simultaneously and continuously updated on the parent corporation's information system.

(5) The drug is prescribed for continuous and uninterrupted use and the pharmacist determines that the drug is being taken properly in accordance with IC 25-26-16.

(6) The pharmacist shall document the following information regarding the refill:

(A) The information required for any refill dispensed under subsection (d).

(B) The dates and times that the pharmacist attempted to contact the prescribing practitioner or the practitioner's designee for consultation and authorization of the prescription refill.

(C) The fact that the pharmacist dispensed the refill without the authorization of a licensed practitioner.

(7) The pharmacist notifies the original prescribing practitioner of the refill and the reason for the refill by the practitioner's next business day after the refill has been made by the pharmacist.

(8) Any pharmacist initiated refill under this subsection may not

be for more than the minimum amount necessary to supply the patient through the prescribing practitioner's next business day. However, a pharmacist may dispense a drug in an amount greater than the minimum amount necessary to supply the patient through the prescribing practitioner's next business day if:

(A) the drug is packaged in a form that requires the pharmacist to dispense the drug in a quantity greater than the minimum amount necessary to supply the patient through the prescribing practitioner's next business day; or

(B) the pharmacist documents in the patient's record the amount of the drug dispensed and a compelling reason for dispensing the drug in a quantity greater than the minimum amount necessary to supply the patient through the prescribing practitioner's next business day.

(9) Not more than one (1) pharmacist initiated refill is dispensed under this subsection for a single prescription.

(10) The drug prescribed is not a controlled substance.

A pharmacist may not refill a prescription under this subsection if the practitioner has designated on the prescription form the words "No Emergency Refill". ~~This subsection expires June 30, 2003.~~

(d) When refilling a prescription, the refill record shall include:

(1) the date of the refill;

(2) the quantity dispensed if other than the original quantity; and

(3) the dispenser's identity on:

(A) the original prescription form; or

(B) another board approved, uniformly maintained, readily retrievable record.

(e) The original prescription form or the other board approved record described in subsection (d) must indicate by the number of the original prescription the following information:

(1) The name and dosage form of the drug.

(2) The date of each refill.

(3) The quantity dispensed.

(4) The identity of the pharmacist who dispensed the refill.

(5) The total number of refills for that prescription.

(f) A prescription is valid for not more than one (1) year after the original date of issue.

(g) A pharmacist may not knowingly dispense a prescription after the demise of the practitioner, unless in the pharmacist's professional judgment it is in the best interest of the patient's health.

(h) A pharmacist may not knowingly dispense a prescription after the demise of the patient.

(i) A pharmacist or a pharmacy shall not resell, reuse, or redistribute a medication that is returned to the pharmacy after being dispensed unless the medication:

(1) was dispensed to a patient residing in an institutional facility (as defined in 856 IAC 1-28-1(a));

(2) was properly stored and securely maintained according to sound pharmacy practices;

(3) is returned unopened and:

(A) was dispensed in the manufacturer's original:

(i) bulk, multiple dose container with an unbroken tamper resistant seal; or

(ii) unit dose package; or

(B) was packaged by the dispensing pharmacy in a:

(i) multiple dose blister container; or

(ii) unit dose package;

(4) was dispensed by the same pharmacy as the pharmacy accepting the return;

(5) is not expired; and

(6) is not a controlled substance (as defined in IC 35-48-1-9), unless the pharmacy holds a Type II permit (as described in IC 25-26-13-17).

(j) A pharmacist may use the pharmacist's professional judgment as to whether to accept medication for return under subsection ~~(h).~~ **(i).**

(k) A pharmacist who violates subsection (c) commits a Class A infraction.

SECTION 5. IC 35-48-7-2, AS AMENDED BY P.L.107-1999, SECTION 1, IS AMENDED TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2003]: Sec. 2. As used in this chapter, "central repository" refers to the central repository designated by the ~~state police department~~ **advisory committee** under section 10 of this chapter.

SECTION 6. IC 35-48-7-8, AS AMENDED BY P.L.107-1999, SECTION 2, IS AMENDED TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2003]: Sec. 8. The ~~state police department, with the approval of the~~ advisory committee shall provide for a controlled substance prescription monitoring program that includes the following components:

(1) Each time a controlled substance designated by the advisory committee under IC 35-48-2-5 through IC 35-48-2-10 is dispensed, the dispenser shall transmit to the central repository the following information:

(A) The recipient's name.

(B) The recipient's or the recipient representative's

identification number.

(C) The recipient's date of birth.

(D) The national drug code number of the controlled substance dispensed.

(E) The date the controlled substance is dispensed.

(F) The quantity of the controlled substance dispensed.

(G) The number of days of supply dispensed.

(H) The dispenser's United States Drug Enforcement Agency registration number.

(I) The prescriber's United States Drug Enforcement Agency registration number.

(J) An indication as to whether the prescription was transmitted to the pharmacist orally or in writing.

(2) The information required to be transmitted under this section must be transmitted not more than fifteen (15) days after the date on which a controlled substance is dispensed.

(3) A dispenser shall transmit the information required under this section by:

(A) an electronic device compatible with the receiving device of the central repository;

(B) a computer diskette;

(C) a magnetic tape; or

(D) a pharmacy universal claim form;

that meets specifications prescribed by the advisory committee.

(4) The advisory committee may require that prescriptions for controlled substances be written on a one (1) part form that cannot be duplicated. However, the advisory committee may not apply such a requirement to prescriptions filled at a pharmacy with a Type II permit (as described in IC 25-26-13-17) and operated by a hospital licensed under IC 16-21, or prescriptions ordered for and dispensed to bona fide enrolled patients in facilities licensed under IC 16-28. The committee may not require multiple copy prescription forms and serially numbered prescription forms for any prescriptions written. The committee may not require different prescription forms for any individual drug or group of drugs. Prescription forms required under this subdivision must be jointly approved by the committee and by the Indiana board of pharmacy established by IC 25-26-13-3.

(5) The costs of the program.

SECTION 7. IC 35-48-7-9, AS AMENDED BY P.L.107-1999, SECTION 3, IS AMENDED TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2003]: Sec. 9. (a) The ~~state police department~~ **health**

professions bureau or the central repository is responsible for the costs of the program, including the following costs:

(1) Telephone access charges, line charges, and switch charges for transmission of data by dispensers to the central repository.

(2) Purchase of modems and other hardware required for program participation.

(3) Software and software modifications to allow dispensers to participate in the program.

(b) A dispenser may not be penalized for failure to comply with the program if the ~~state police department~~ **health professions bureau** or the central repository cannot secure adequate funding to implement the program and cover the costs under subsection (a).

SECTION 8. IC 35-48-7-10, AS AMENDED BY P.L.107-1999, SECTION 4, IS AMENDED TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2003]: Sec. 10. (a) The ~~state police department, with the advice of the~~ advisory committee shall designate a central repository for the collection of information transmitted under section 8 of this chapter.

(b) The central repository shall do the following:

(1) Create a data base for information required to be transmitted under section 8 of this chapter in the form required under rules adopted by the advisory committee, including search capability for the following:

(A) A recipient's name.

(B) A recipient's or recipient representative's identification number.

(C) A recipient's date of birth.

(D) The national drug code number of a controlled substance dispensed.

(E) The dates a controlled substance is dispensed.

(F) The quantities of a controlled substance dispensed.

(G) The number of days of supply dispensed.

(H) A dispenser's United States Drug Enforcement Agency registration number.

(I) A prescriber's United States Drug Enforcement Agency registration number.

(J) Whether a prescription was transmitted to the pharmacist orally or in writing.

(2) Provide the ~~state police department and the~~ advisory committee with continuing twenty-four (24) hour a day on-line access to the data base maintained by the central repository.

(3) Secure the information collected by the central repository and

the data base maintained by the central repository against access by unauthorized persons.

(4) If the relationship between the ~~state police department~~ **advisory committee** and the central repository is terminated by statute, provide to the ~~state police department and the~~ advisory committee, within a reasonable time, all collected information and the data base maintained by the central repository.

(c) The ~~state police department, with the advice of the~~ advisory committee may execute a contract with a vendor designated by the ~~state police department~~ **advisory committee** as the central repository under this section, or the ~~state police department or~~ advisory committee may act as the central repository under this chapter.

(d) The central repository may gather prescription data from the Medicaid retrospective drug utilization review program (DUR) established by IC 12-15-35.

(e) The ~~state police department and the~~ advisory committee may accept and designate grants, public and private financial assistance, and licensure fees to provide funding for the central repository.

SECTION 9. IC 35-48-7-13, AS AMENDED BY P.L.107-1999, SECTION 5, IS AMENDED TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2003]: Sec. 13. (a) The controlled substances data fund is established to fund the operation of the central repository. The fund shall be administered by the ~~state police department.~~ **health professions bureau.**

(b) Expenses of administering the fund shall be paid from money in the fund. The fund consists of grants, public and private financial assistance, and ~~licensure~~ **sixteen percent (16%) of the controlled substances registration** fees **imposed under IC 35-48-3-1.**

(c) The treasurer of state shall invest the money in the fund not currently needed to meet the obligations of the fund in the same manner as other public money may be invested.

(d) Money in the fund at the end of a state fiscal year does not revert to the state general fund.

SECTION 10. **An emergency is declared for this act.**

COMMITTEE REPORT

Mr. Speaker: Your Committee on Public Health, to which was referred House Bill 1438, has had the same under consideration and begs leave to report the same back to the House with the recommendation that said bill be amended as follows:

Page 3, line 14, reset in roman "for".

Page 3, line 14, after "issuance" insert "**one (1) year**".

Page 3, line 15, reset in roman "for an additional".

Page 3, line 15, delete "until an" and insert "**year until the**".

Page 3, line 17, delete "The expiration date must occur during an".

Page 3, delete line 18.

Page 4, between lines 5 and 6, begin a new paragraph and insert:

"SECTION 5. IC 25-26-13-25, AS AMENDED BY P.L.1-2002, SECTION 98, IS AMENDED TO READ AS FOLLOWS [EFFECTIVE UPON PASSAGE]: Sec. 25. (a) All original prescriptions, whether in written or electronic format, shall be numbered and maintained in numerical and chronological order, or in a manner approved by the board and accessible for at least two (2) years in the pharmacy. A prescription transmitted from a practitioner by means of communication other than writing must immediately be reduced to writing or recorded in an electronic format by the pharmacist. The files shall be open for inspection to any member of the board or its duly authorized agent or representative.

(b) Except as provided in subsection (c) before the expiration of subsection (c) on June 30, 2003, a prescription for any drug, the label of which bears either the legend, "Caution: Federal law prohibits dispensing without prescription" or "Rx Only", may not be refilled without written or oral authorization of a licensed practitioner.

(c) A prescription for any drug, the label of which bears either the legend, "Caution: Federal law prohibits dispensing without prescription" or "Rx Only", may be refilled by a pharmacist one (1) time without the written or oral authorization of a licensed practitioner if all of the following conditions are met:

(1) The pharmacist has made every reasonable effort to contact the original prescribing practitioner or the practitioner's designee for consultation and authorization of the prescription refill.

(2) The pharmacist believes that, under the circumstances, failure to provide a refill would be seriously detrimental to the patient's health.

(3) The original prescription authorized a refill but a refill would otherwise be invalid for either of the following reasons:

(A) All of the authorized refills have been dispensed.

(B) The prescription has expired under subsection (f).

(4) The prescription for which the patient requests the refill was:

(A) originally filled at the pharmacy where the request for a refill is received and the prescription has not been transferred for refills to another pharmacy at any time; or

(B) filled at or transferred to another location of the same pharmacy or its affiliate owned by the same parent corporation if the pharmacy filling the prescription has full access to prescription and patient profile information that is simultaneously and continuously updated on the parent corporation's information system.

(5) The drug is prescribed for continuous and uninterrupted use and the pharmacist determines that the drug is being taken properly in accordance with IC 25-26-16.

(6) The pharmacist shall document the following information regarding the refill:

(A) The information required for any refill dispensed under subsection (d).

(B) The dates and times that the pharmacist attempted to contact the prescribing practitioner or the practitioner's designee for consultation and authorization of the prescription refill.

(C) The fact that the pharmacist dispensed the refill without the authorization of a licensed practitioner.

(7) The pharmacist notifies the original prescribing practitioner of the refill and the reason for the refill by the practitioner's next business day after the refill has been made by the pharmacist.

(8) Any pharmacist initiated refill under this subsection may not be for more than the minimum amount necessary to supply the patient through the prescribing practitioner's next business day. However, a pharmacist may dispense a drug in an amount greater than the minimum amount necessary to supply the patient through the prescribing practitioner's next business day if:

(A) the drug is packaged in a form that requires the pharmacist to dispense the drug in a quantity greater than the minimum amount necessary to supply the patient through the prescribing practitioner's next business day; or

(B) the pharmacist documents in the patient's record the amount of the drug dispensed and a compelling reason for dispensing the drug in a quantity greater than the minimum amount necessary to supply the patient through the prescribing practitioner's next business day.

(9) Not more than one (1) pharmacist initiated refill is dispensed under this subsection for a single prescription.

(10) The drug prescribed is not a controlled substance.

A pharmacist may not refill a prescription under this subsection if the practitioner has designated on the prescription form the words "No Emergency Refill". ~~This subsection expires June 30, 2003.~~

(d) When refilling a prescription, the refill record shall include:

(1) the date of the refill;

(2) the quantity dispensed if other than the original quantity; and

(3) the dispenser's identity on:

(A) the original prescription form; or

(B) another board approved, uniformly maintained, readily retrievable record.

(e) The original prescription form or the other board approved record described in subsection (d) must indicate by the number of the original prescription the following information:

(1) The name and dosage form of the drug.

(2) The date of each refill.

(3) The quantity dispensed.

(4) The identity of the pharmacist who dispensed the refill.

(5) The total number of refills for that prescription.

(f) A prescription is valid for not more than one (1) year after the original date of issue.

(g) A pharmacist may not knowingly dispense a prescription after the demise of the practitioner, unless in the pharmacist's professional judgment it is in the best interest of the patient's health.

(h) A pharmacist may not knowingly dispense a prescription after the demise of the patient.

(i) A pharmacist or a pharmacy shall not resell, reuse, or redistribute a medication that is returned to the pharmacy after being dispensed unless the medication:

(1) was dispensed to a patient residing in an institutional facility (as defined in 856 IAC 1-28-1(a));

(2) was properly stored and securely maintained according to sound pharmacy practices;

(3) is returned unopened and:

(A) was dispensed in the manufacturer's original:

(i) bulk, multiple dose container with an unbroken tamper resistant seal; or

(ii) unit dose package; or

(B) was packaged by the dispensing pharmacy in a:

(i) multiple dose blister container; or

(ii) unit dose package;

(4) was dispensed by the same pharmacy as the pharmacy accepting the return;

(5) is not expired; and

(6) is not a controlled substance (as defined in IC 35-48-1-9), unless the pharmacy holds a Type II permit (as described in IC 25-26-13-17).

(j) A pharmacist may use the pharmacist's professional judgment as to whether to accept medication for return under subsection ~~(h).~~ **(i).**

(k) A pharmacist who violates subsection (c) commits a Class A infraction.".

Page 7, after line 13, begin a new paragraph and insert:

"SECTION 11. **An emergency is declared for this act.**".

Renumber all SECTIONS consecutively.

and when so amended that said bill do pass.

(Reference is to HB 1438 as introduced.)

BROWN C, Chair

Committee Vote: yeas 10, nays 0.

SENATE MOTION

Mr. President: I move that Senator Skinner be added as cosponsor of Engrossed House Bill 1438.

DILLON

COMMITTEE REPORT

Mr. President: The Senate Committee on Health and Provider Services, to which was referred House Bill No. 1438, has had the same under consideration and begs leave to report the same back to the Senate with the recommendation that said bill be AMENDED as follows:

Delete the title and insert the following:

A BILL FOR AN ACT to amend the Indiana Code concerning professions and occupations.

Page 2, delete lines 25 through 42.

Page 3, delete lines 1 through 2.

Page 3, line 34, delete "account established by section 6.5 of this chapter." and insert "**state general fund.**".

Page 4, line 2, delete "cost" and insert "**amount**".

Page 10, line 6, after "fees" insert "**imposed**".

Renumber all SECTIONS consecutively.

and when so amended that said bill do pass.

(Reference is to HB 1438 as printed January 31, 2003.)

MILLER, Chairperson

Committee Vote: Yeas 6, Nays 0.